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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,142	02/27/2004	Clement Wan Chye Meng	P-5169D11	9263
26253	7590	09/21/2004	EXAMINER	
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/789,142

Applicant(s)

MENG ET AL.

Examiner

Anu Ramana

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "33" has been used to designate both the notch and the introducer needle (Fig. 3). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

Claim 10 is objected to because of the following informalities. In line 2, it appears that "an adapter" should be "a catheter adapter" for clarity. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 10 and 15, the functional recitation, "a proximal end of the septum housing is adapted to prevent the attachment of a medical device to the proximal end of the catheter adapter," is indefinite because it is not supported by recitation in the claim of sufficient structure

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to accomplish the function. The septum housing can accept a medical device with a piercing end such as a needle.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6-10 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Genese et al. (US 4,496,348).

Genese et al. disclose a catheter assembly 10 including a catheter 12, a catheter hub 14 attached to a proximal end of catheter 12, a needle 18 having a needle hub 20 attached to the proximal end 22 of needle 18 and an elastic sealing member or “elastomeric septum” 30 within a slide with a retaining member or “housing” (42, 44A, 46A and 49) (Fig. 4E, col. 7, lines 4-25 and lines 62-68 and col. 8, lines 1-10).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5 and 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al. (US 6,551,283) in view of Genese et al. (US 4,496,348).

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Guo et al. disclose a cannula or "catheter" assembly 70 with an introducer sheath or "catheter" 100 attached to a hub or "adapter" 90, a valve gasket or "septum" 20 with a centering hole or "cavity" 24, a cap or "septum housing" 80 wherein the housing extends over a portion of the proximal face of the septum and an elongated cylindrical medical device 120 disposed in the sheath 100 (Figures 1 and 10, col. 5, lines 32-67, col. 6, lines 1-64, col. 9, lines 11-67 and col. 10, lines 1-15).

Guo et al. disclose all elements of the claimed invention except that the elongated cylindrical medical device is a needle.

Genese et al. teach that it is known in the art to provide an elongated cylindrical medical device such as a needle with a needle hub in a catheter hub for insertion of a catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a needle with a needle hub in the Guo et al. assembly, as taught by Genese et al., for the purpose of catheter insertion.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of Meng et al. (U.S. 6,506,181) in view of Genese et al. (US 4,496,348).

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Patented claim 12 discloses all elements of the claimed invention except for a proximal end of the septum holder or "housing" extending over at least a portion of the proximal face of the septum.

Genese et al. teach a septum housing with a retaining member 49 covering the proximal face of a sealing member or "septum" 30 to hold the sealing member inside a catheter hub by an interference or friction fit (Fig. 4E, col. 7, lines 4-25 and lines 62-68 and col. 8, lines 1-10).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a housing in the invention of claim 12 such that a portion of the housing covers a proximal face of the septum, as taught by Genese et al., to retain the septum inside the hub.

Regarding claims 5, 6, 11, 12 and 18, the Applicants do not disclose the criticality of the extent or "length" of the septum housing. It would have been an obvious matter of design choice to change the length of the septum housing, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 10-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of Meng et al. (U.S. 6,719,726) in view of Genese et al. (US 4,496,348).

Patented claim 11 discloses all elements of the claimed invention except for an adapter and a proximal end of the septum holder or "housing" extending over at least a portion of the proximal face of the septum.

Genese et al. teach a septum housing with a retaining member 49 covering the proximal face of a sealing member or "septum" 30 to hold the sealing member inside a catheter hub or "adapter" by an interference or friction fit (Fig. 4E, col. 7, lines 4-25 and lines 62-68 and col. 8, lines 1-10).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a housing in the invention of patented claim 11 such that a portion of the housing covers a proximal face of the septum, as taught by Genese et al., to retain the septum inside the hub.

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Regarding claim 11, the Applicants do not disclose the criticality of the extent or "length" of the septum housing. It would have been an obvious matter of design choice to change the length of the septum housing, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anu Ramana*  
September 17, 2004

*Kevin Shaver*  
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